K012944

1 510(k) SUMMARY PER 21 CFR 807.92

This chapter contains commercial and confidential trade secret information and we respectfully request maximum protection provided by the law. Please refer to chapter INDICATIONS FOR USE, where you will find MediTeam Dental AB's official statement to be published on the World Wide Web.

Please note that the trade name "Carisolv" is mentioned in parts of the technical documentation (the Power drive is referred by MediTeam's subcontractor Schlumbohm OHG as "Carisolv Unit 3.01", see Appendix C, D, and E), and that a supplement to the PMA P000005 for the device "Carisolv Power drive" has been submitted in July 2001.

In accordance with 21 CFR 807.92, the following information constitutes the MediTeam Dental AB's summary for the Power drive.

1.1 Submitter

Submitter's Name:	MediTeam Dental AB (publ)
Address:	Göteborgsvägen 74
	S-433 63 Sävedalen
	Sweden
Contact Person:	Thomas Stjernkvist, M.Sc.
	Vice President Quality Assurance
Direct dial:	+46-31-336 91 03
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E.mail:	thomas.stjernkvist@mediteam.com

1.2 Date

510(k) Summary has been prepared on August 30th, 2001.

1.3 Reason for 510(k) submission

It is intended to put this device into commercial distribution for the first time in the US.

1.4 Trade Name

Power drive

1.5 Classification Name

Dental Handpiece and Accessories (21 CFR 872.4200)

1.6 Classification

The device is a general control of class I according to 21 CFR 872.4200
Product Code: EKX

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 0 2001

Mr. Thomas Stjernkvist
Vice President Quality Assurance
MediTeam AB
Goteborgsvagen 74,
Savedalen,
SWEDEN

Re: K012944
Trade/Device Name: Power Drive
Regulation Number: 872.4200
Regulation Name: Dental Headpiece and Accessories
Regulatory Class: I
Product Code: EKX
Dated: August 30, 2001
Received: September 14, 2001

Dear Mr. Stjernkvist:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

MediTeam

NOV 2 0 2001

MediTeam Dental AB

INDICATIONS FOR USE

510(k) Number K012944

Device Name: Power drive

Indications for Use:

The Power drive System is a small battery-powered device, light-weight, low speed electric motor handpiece, runs at 350 rpm to 450 rpm with a maximum torque of 12mNm, and is intended for use in light general dental works where low speed and low torque is required.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use _____
(Per 21 CFR 801.109)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
General Hospital Devices
(Division) Number K012944